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Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GARY KRANTZ, S.T. CHEN,
ADAM ZIPP and JOANNE ZENG

Appeal No. 1996-3973
Application No. 08/048,657

ON BRIEF

Before PAK, WARREN, and SPIEGEL, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 19, which are all of the claims pending in this application. A copy of claims 1-19 is attached as an appendix to this decision.

The references relied on by the examiner are:

Moyer et al. (Moyer)	3,783,105	Jan. 1, 1974
Przybylowicz et al. (Przybylowicz)	3,992,158	Nov. 16, 1976
Schaeffer et al. (Schaeffer)	4,110,079	Aug. 29, 1978
Piejko et al. (Piejko)	4,780,411	Oct. 25, 1988
Daffern et al. (Daffern)	4,994,238	Feb. 19, 1991
Kumar et al. (Kumar) (published European patent application)	0 141 648	May 15, 1985

References relied on by this merits panel are:

Kato et al. (Kato)	H930	Jun. 4, 1991
Evans et al. (Evans)	4,737,457	Apr. 12, 1988
Phillips et al. (Phillips)[1]	4,935,346	Jun. 19, 1990

A. Eggert, *ELECTRONICS AND INSTRUMENTATION FOR THE CLINICAL LABORATORY*, 291-292 (John Wiley & Sons, New York, 1983) (Eggert).

Ngo et al. (Ngo), "A Sensitive and Versatile Chromogenic Assay for Peroxidase and Peroxidase-Coupled Reactions," 105 *Analytical Biochemistry* 389-397 (1980).

TEXTBOOK OF CLINICAL CHEMISTRY 248 (N. Tietz, ed., W.B. Saunders Company, Philadelphia, 1986) (Tietz).

ISSUES[2]

(I) Claims 1, 3, 4, 6, 8, 9 and 11-13 stand rejected under 35 U.S.C. § 103 as being unpatentable over Daffern in view of Moyer. **(II)** Claims 2, 5, 7 and 10 stand rejected under

[1]Phillips was incorporated by reference into appellants' specification (see e.g., page 7, lines 10-11).

[2]The examiner has withdrawn the final rejection of claim 13 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure, "in view of the arguments presented" in appellants' brief (answer, page 2).

35 U.S.C. § 103 as being unpatentable over **(I)** further in view of any of Piejko, Kumar, Schaeffer or Przybylowicz. **(III)** Claims 14-19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Przybylowicz in view of Moyer.

We reverse the examiner's rejections and institute new grounds of rejection under 37 C.F.R. § 1.196(b).

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's answer (Paper No. 20, mailed June 11, 1996), to the examiner's supplemental answer (Paper No. 22, mailed October 1, 1996), to the examiner's second supplemental answer (Paper No. 24, mailed December 17, 1996) and to the examiner's third supplemental answer (Paper No. 26, mailed February 13, 1997) for the examiner's reasoning in support of the rejections and to the appellants' brief (Paper No. 19, filed May 17, 1996), to the appellants' reply brief (Paper No. 21, filed July 16, 1996), to the appellants' second reply brief (Paper No. 23, filed October 15, 1996) and to the appellants' third reply brief (Paper No. 25, filed January 6, 1997) for the appellants' arguments thereagainst.

THE INVENTION

The claimed invention is directed to a multilayered test strip for determining an analyte or "active species," e.g., glucose, (claims 1-13 and 17-19) and to its manufacture (claims 14-16). The test strip comprises (i) an apertured inert backing layer overlying (ii) a one or two layered

"reactive unit" comprising a spreading agent and an analyte-reactive reagent and (iii) an indicator layer comprising an indicator reagent impregnated into a porous substrate. For example, when determining glucose with a two-layered reactive unit test strip, a drop of liquid sample, e.g., blood, is applied to a top layer comprising the spreading agent through the aperture. This "spreading" layer allows the applied drop to spread out and penetrate through into a second layer comprising the reactive reagent. The penetrating sample dissolves the reactive reagent and glucose in the sample reacts therewith to form a reaction product which then penetrates through into a bottom indicator layer where it dissolves and reacts with an indicator reagent to produce a detectable product, e.g., a dye, which is indicative of the glucose in the sample.

A preferred reactive reagent comprises a mixture of glucose oxidase, peroxidase and MBTH (3-methyl-2-benzothizolinone hydrazone hydrochloride) (specification, page 12, lines 20-34). A preferred indicator reagent comprises DMAB (3-dimethylaminobenzoic acid) (specification, sentence bridging pages 11-12). Preferred spreading agents include polyoxyethylene ether and diatomaceous earth (specification, page 13, lines 20-22 and page 14, lines 16-26). Preferably, the porous substrate is a nylon membrane (specification, page 11, lines 26-28).

According to the specification, the claimed test strip has two innovations over the prior art: (1) the indicator reagent and the reactive reagent are placed into two separate layers so that they cannot interact chemically during storage prior to use and (2) a spreading layer is provided

to improve spreading of the liquid sample droplet over the upper layer after it is placed in the aperture (specification, page 4, last paragraph through page 5, first full paragraph).

OPINION

The examiner bears the initial burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, there must be both some suggestion or motivation to modify the reference or combine reference teachings and a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). Furthermore, the prior art must teach or suggest all of the claimed limitations.

I. *Rejection of claims 1, 3, 4, 6, 8, 9 and 11-13 over Daffern in view of Moyer*

Daffern describes a test device comprising, in sequence, an absorbent layer **2**, a barrier layer **8**, and a reagent matrix layer **6** having a defined saturation volume, wherein the absorbent and barrier layers each have an opening **14** for applying a test sample directly onto the reagent layer (Fig. 1; col. 2, lines 6-11). The reagents in the reagent matrix are selected based on the analyte to be determined, e.g., glucose oxidase, a substance having peroxidase activity, and an oxidizable indicator (e.g., 3,5-dimethylaminobenzoic acid (DMAB), 3-methyl-2-benzothiazolinone hydrochloride (MBTH), and/or tetramethyl benzadine (TMB)) for measuring glucose in a body fluid (col. 6, lines 39-48; col. 7, lines 3-17).

Moyer describes a test device comprising a plurality of superposed test reagent impregnated members, including in descending sequence, a top porous glass fiber disc **18**; an

intermediate porous glass fiber disc **20**; a lower porous glass fiber disc **22**; a porous filter membrane **26** (e.g., a cellulose acetate membrane); and a transparent film membrane **30**, wherein a first reagent is absorbed on discs **18, 20** and **22** and a second reagent is freeze-dried on the inner surface of membrane **30** (Fig. 3; col. 4, lines 38-61). EXAMPLE 3 (col. 6) illustrates a test device for determining hexokinase wherein the upper glass fiber discs are impregnated with NADP, G-6-P, magnesium acetate, PMS and NBT (an indicator reagent which reacts to form a detectable formazan dye), while the lower transparent film membrane is coated with G-6-PDH, dextran and, if necessary, hexokinase.

The examiner states "[t]he claims differ from Daffern above in that the claims include multiple layers with a single aligned aperture" and concludes that it would have been obvious to one of ordinary skill in the art "to employ the multiple layer features of the test strip apparatus of Moyer in the test strip of Daffern because related types of reactions are performed by the test strips of both references" (answer, page 5). According to the examiner, "the teachings of the references were clearly in the public domain and one of ordinary skill in this art known of these references could have selected as the Appellants have done" (answer, page 11).

However, the examiner has not pointed out where either Daffern or Moyer discloses or suggests the *specific juxtaposition* of (i) an apertured inert backing layer overlying (ii) a one or two layered "reactive unit" comprising a spreading agent and an analyte-reactive reagent and (iii) an indicator layer comprising an indicator reagent impregnated into a porous substrate. Both

Daffern and Moyer combine the analyte-reactive agent and the indicator reagent in the *same* layer and while the references *could* be combined as the examiner argues, the examiner has failed to provide a reason why the references *should* be combined. The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification. *In re Laskowski*, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398-99 (Fed. Cir. 1989); *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

Furthermore, the examiner's position that "the absorbent and porous layers of the references would appear to function as the presently claimed spreading layer" (answer, page 10) is not well taken. A "spreading" layer is more than a simple application and/or filter layer. Both appellants' specification and the prior art indicate that a "spreading" layer distributes an applied liquid sample so as to provide a uniform concentration of liquid at the surface of the spreading layer facing (see e.g., specification, page 5, lines 10-17; Przybylowicz, col. 3, lines 25-31; Schaeffer, col. 6, lines 44-55). The examiner has failed to establish, on this record, that one of ordinary skill in the art would have reasonably expected the absorbent and porous layers of the references to function as a spreading layer, i.e., to promote the spreading of an applied sample droplet over the surface of the layer exposed through the aperture as required by the claimed invention.

Finally, the examiner has failed to point out and we do not find where Daffern and/or Moyer disclose or suggest a *combined* spreading and reactive reagent layer containing both a spreading agent and an analyte-reactive agent.

Based on the foregoing, we conclude that the examiner has not established a *prima facie* case of obviousness as to claims 1, 3, 4, 6, 8, 9 and 11-13 over Daffern in view of Moyer. Having concluded that the examiner has not established a *prima facie* case of obviousness, we do not reach appellants' discussion of rebuttal evidence on page 4 of the reply brief.

II. *Rejection of claims 2, 5, 7 and 10 over the above combination of Daffern in view of Moyer taken further in view of any of Piejko, Kumar, Schaeffer or Przybylowicz*

The examiner relies on Piejko, Kumar, Schaeffer or Przybylowicz to establish the obviousness of using a nylon membrane as the porous substrate of claims 2 and 7 and of using either cellulose acetate or diatomaceous earth as the spreading agent of claims 5 and 10 (answer, page 8).

However, as to Piejko, the examiner has not explained why one of ordinary skill in the art would have specifically selected either polyamides or cellulose acetate from the list of film-forming, water-insoluble organic polymers (col. 6, lines 5-35) used to form a membrane for detection reagent incorporation or where Piejko discloses or suggests cellulose acetate as a spreading agent. Furthermore, like Daffern and Moyer, example 56 in Piejko discloses combining the analyte-reactive agent and the indicator reagent in the *same* layer. Kumar similarly describes "the combination of a complete reagent system and a reflective component in a *single* layer" (emphasis added, page 5, lines 2-4) (see also page 9, lines 4-18 wherein all reagents necessary for a glucose determination are *simultaneously* provided in the reagent matrix). Again, the examiner has not explained why one of ordinary skill in the art would have

specifically selected either diatomaceous earth from Kumar's list of suitable reflective particles (page 8, lines 7-16) or cellulose acetate from Kumar's list of binders (page 10, lines 30-36) for use as a spreading agent in a *multilayered* test strip. While Schaeffer and Przybylowicz both describe diatomaceous earth, cellulose acetate and polyamide as suitable particulate materials for forming spreading layers (in Schaeffer see col. 12, line 45 - col. 13, line 21 and in Przybylowicz see col. 7, lines 8-64 and col. 15, lines 36-38), the examiner has not pointed out and we do not find where either reference discloses or suggests a polyamide, i.e., nylon, porous matrix impregnated with indicator reagent as claimed. It appears that the examiner is again using the wrong standard of patentability under § 103, i.e., what *could* be combined from the references, without providing any reason why the references *should* be combined. Finally, the examiner has not established, on this record, how the combined disclosures of Daffern, Moyer and any one or more of Piejko, Kumar, Schaeffer or Przybylowicz would have disclosed or suggested the specifically claimed juxtaposition of layers and apertured backing to one of ordinary skill in the art.

Therefore, we conclude that the examiner has not established a *prima facie* case of obviousness of claims 2, 5, 7 and 10 over Daffern in view of Moyer taken further in view of any of Piejko, Kumar, Schaeffer or Przybylowicz.

III. *Rejection of claims 14-19 over Przybylowicz in view of Moyer*

The examiner has failed to address all of the substantive limitations of claims 14-19. For example, the examiner has not pointed out where either Przybylowicz or Moyer discloses or

suggests (a) the DMAB indicator or (b) the relative viscosities of the applied indicator and reactive reagent solutions of independent claim 14. Therefore, we conclude that the examiner has not established a *prima facie* case of obviousness of claims 14-19 over Przybylowicz in view of Moyer.

NEW GROUNDS OF REJECTION - 37 C.F.R.. § 1.196(b)

Claim 13 is rejected under 35 U.S.C. § 102(b) as anticipated by Tietz, taken in light of Przybylowicz. According to Tietz, the Kodak Ektachem analyzer of Eastman Kodak Company uses a multilayered, 16-mm square test slide in which reagents dispersed in emulsions are activated by diffusion of sample fluid into the layers. From 3-7 layers containing reagents are used for each of the different tests available. Figure 1D-6 shows a schematic, exploded view of the test slide comprising in descending order (1) an apertured upper slide mount, (2) a spreading layer, (3) a reagent layer, (4) a semipermeable layer, (5) an indicator layer, (6) a support layer and (7) an apertured lower slide mount. As to claim 13, the claimed reaction unit layer structure including a spreadability enhancing material means and means for determining the presence of an active species reads on the (2) spreading layer and (3)/(5) reagent and indicator layers of Tietz, respectively, while the claimed backing with aperture reads on the (1) apertured upper slide mount. Przybylowicz, assigned to the Eastman Kodak Company, is cited to establish the definition of a spreading layer (see e.g., col. 3, lines 25-56).

Claims 6 and 9 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans and Tietz. Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over Evans and Tietz, as

applied to claim 6 above, and further in view of Przybylowicz. Evans (also assigned to Eastman Kodak Company) describes a multilayered analytical element (i.e., test strip) for determining glucose comprising a spreading layer containing both a reactive reagent (i.e., glucose oxidase and peroxidase) and a substance promoting the spreading of a liquid (i.e., poly(vinyl pyrrolidone)) overlying a registration layer comprising an indicator reagent (i.e., 2-(benzensulfonylhydrazino-)-5-nitropyridine (see EXAMPLE 13, col. 11). Przybylowicz describes spreading layers comprising poly(vinyl pyrrolidone) (col. 7, lines 28-43) and use of diatomaceous earth and/or cellulose acetate as alternative spreading agents (col. 7, lines 8-64; col. 15, lines 36-40). Tietz has been described above. As to claims 6 and 9, it would have been obvious to one of ordinary skill in the art to incorporate the multilayered analytical element of Evans into the apertured slide mount of Tietz in order to provide a test element/strip capable of automated use. As to claim 10, it would have been further obvious to use diatomaceous earth and/or cellulose acetate as additional/alternative spreading agents in a spreading layer as suggested by Przybylowicz.

Claims 1, 4 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Kato, Przybylowicz and Tietz. Kato describes a multi-layered analytical element for determining glucose comprising a support having thereon in ascending order a reagent layer containing a dye coupler (i.e., an indicator reagent), an enzyme-containing layer containing glucose oxidase and peroxidase and a porous spreading layer (abstract). Spreading layers as described by Przybylowicz can be used, including layers comprising diatomaceous earth (col. 5, lines 22-29). Przybylowicz discloses spreading layers comprising diatomaceous earth and/or cellulose acetate

(col. 7, lines 8-64; col. 15, lines 36-40). Tietz has been described above. It would have been obvious to one of ordinary skill in the art to incorporate the multilayered analytical element of Kato into the apertured slide mount of Tietz in order to provide a test element/strip capable of automated use and to use spreading layers comprising diatomaceous earth and/or cellulose acetate as described by Przybylowicz in view of Kato's express suggestion to use spreading layers as described by Przybylowicz.

Claims 1, 3-5 and 11 are rejected under 35 U.S.C. § 103 as being unpatentable over Tietz and Eggert in view of Przybylowicz and Evans take further in view of Ngo and Phillips. Tietz, Przybylowicz and Evans have been described above. Eggert describes colorimetric slides for use with an Ektachem analyzer. The colorimetric slides comprise in descending order (a) a top diffusion (i.e., spreading) layer which allows an applied sample drop to spread out and penetrate through at a controlled rate, (b) a chemical or enzyme (i.e., reagent) layer where the reaction takes place, (c) a dye or color layer (i.e., indicator layer) where dye-coupled and two stage reactions form a measurable compound and (d) a slide support. Przybylowicz describes spreading layers comprising diatomaceous earth and/or cellulose acetate (col. 7, lines 8-64; col. 15, lines 36-40), suggests that multi-stage reactions analysis can best be accomplished in an element having a plurality of reagent layers, each of which may be adapted to enhance or effect particular reaction stages (col. 12, lines 14-18), e.g., by separating reagents into separate, discrete layers (col. 12, lines 29-31), and describes determining glucose using a reagent layer comprising glucose oxidase, peroxidase and *o*-dianisidine (col. 15, lines 23-25). Like Evans, Ngo and

Phillips both describe determining glucose in human sera/blood using a coupled glucose oxidase - peroxidase enzyme system and an oxygen acceptor, e.g., 3-methyl-2-benzothiazolione hydrazone (MBTH) (see page 392-384 in Ngo and col. 6, lines 45-65 in Phillips). Both Ngo and Phillips additionally couple MBTH to 3-(dimethylamino)benzoic acid (DMAB). According to Ngo use of the MBTH-DMAB couple increases the sensitivity and versatility of the glucose assay and is safer because MBTH-DMAB are not carcinogenic like other reagents, e.g., *o*-diansidine, widely used as chromogens for peroxidase-catalyzed reactions (abstract; page 394). According to Phillips, use of the MBTH-DMAB couple allows for correction of hematocrit and degree of oxygenation of blood (col. 10, lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art to modify the generic test slide described by Tietz or Eggert to assay for a clinically significant analyte, i.e., glucose, using a conventional glucose oxidase-peroxidase-MBTH reagent system as described by Evans, Ngo and Phillips, and to further use an MBTH-DMAB couple as suggested by Ngo and Phillips to improve the sensitivity, versatility, safety and specificity of the assay, wherein the enzyme and chromogen reactions are separated into an enzyme and a dye-couple layers, respectively, as suggested by Eggert, and because Przybylowicz suggests that separation of reaction steps into separate, discrete layers can enhance the overall assay reaction.

Claims 1, 2 and 14-19 are rejected under 35 U.S.C. § 103 as being unpatentable over Przybylowicz, Phillips, Eggert and Tietz. Przybylowicz, Phillips, Eggert and Tietz have been discussed above. Przybylowicz also describes conventional processes for preparing multilayered

elements (i.e., test strips), including coating an initial layer on a support and thereafter coating successive layers directly on those coated previously and adjusting coating formulations to keep adjacent layers discrete and to minimize or eliminate interlayer component migration (col. 9, lines 13-41). Phillips describes applying an MBTH-DMAB dye solution to a porous nylon matrix support, drying and then applying a low viscosity enzyme solution comprising glucose oxidase and peroxidase thereto followed by drying (col. 11, line 34 - col. 12, line 13). Thus, it would have been obvious to one of ordinary skill in the art to modify the generic test slide described by Tietz or Eggert to assay for a clinically significant analyte, i.e., glucose, using a conventional glucose oxidase-peroxidase-MBTH-DMAB reagent dye couple system as described by Ngo and Phillips to improve the sensitivity, versatility, safety and specificity of the assay, wherein the enzyme and chromogen reactions are separated into an enzyme and a dye-couple layers, respectively, as suggested by Eggert, and because Przybylowicz suggests that separation of reaction steps into separate, discrete layers can enhance the overall assay reaction. It would have been further both conventional and within ordinary skill in the art to coat an initial dye layer comprising MBTH-DMAB on a support, such as nylon, and thereafter coat successive layers, including an overlying enzyme layer comprising glucose oxidase and peroxidase using a higher viscosity enzyme solution to maintain a separate, discrete enzyme layer, thereby minimizing or eliminating interlayer component migration, as suggested by Eggert, Tietz, Przybylowicz and Phillips.

Claims 7 and 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans and Tietz, as applied to claim 6 above, and further in view of Ngo and Phillips. Claim 12 is rejected under 35 U.S.C. § 103 as being unpatentable over Evans, Przybylowicz and Tietz taken further in view of Ngo and Phillips. Evans, Przybylowicz, Tietz, Ngo and Phillips have been described above. As to claims 8 and 12, it would have been obvious to one of ordinary skill in the art to modify the multilayered analytical element/test slide of Evans-Przybylowicz-Tietz discussed above by coupling the MBTH of Evans to the DMAB of Ngo or Phillips, to improve the sensitivity, versatility, safety and specificity of the assay as suggested by Ngo and Phillips. As to claim 7, it would have been further obvious to use nylon as the support layer of Evans in the Evans-Tietz test slide because Phillips discloses nylon as a strong and stable support material compatible with an MBTH-DMAB dye couple (col. 11, lines 35-38).

CONCLUSION

To summarize, the decision of the examiner **(I)** to reject claims 1, 3, 4, 6, 8, 9 and 11-13 under 35 U.S.C. § 103 as being unpatentable over Daffern in view of Moyer, **(II)** to reject claims 2, 5, 7 and 10 under 35 U.S.C. § 103 as being unpatentable over Daffern in view of Moyer and further in view of any of Piejko, Kumar, Schaeffer or Pryzybylowicz, and **(III)** to reject claims 14-19 under 35 U.S.C. § 103 as being unpatentable over Przybylowicz in view of Moyer is reversed.

Pursuant to the provisions of 37 CFR § 1.196(b), the following new grounds of rejection have been made. Claim 13 is rejected under 35 U.S.C. § 102(b) as anticipated by Tietz, taken in light of Przybylowicz. Claims 6 and 9 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans and Tietz. Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over Evans and Tietz, as applied to claim 6 above, and further in view of Przybylowicz. Claims 1, 4 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Kato, Przybylowicz and Tietz. Claims 1, 3-5 and 11 are rejected under 35 U.S.C. § 103 as being unpatentable over Tietz and Eggert in view of Przybylowicz and Evans and taken further in view of Ngo and Phillips. Claims 1, 2 and 14-19 are rejected under 35 U.S.C. § 103 as being unpatentable over Przybylowicz, Phillips, Eggert and Tietz. Claims 7 and 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans and Tietz, as applied to claim 6 above, and further in view of Ngo and Phillips. Claim 12 is rejected under 35 U.S.C. § 103 as being unpatentable over Evans, Przybylowicz and Tietz taken further in view of Ngo and Phillips.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53, 131, 53, 197 (Oct. 10, 1997), 1203 off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 C.F.R. § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the two following options with respect to new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner ....
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record ...

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED- 37 C.F.R. § 1.196(b)

CHUNG K. PAK Administrative Patent Judge	)
CHARLES F. WARREN Administrative Patent Judge	) BOARD OF PATENT) APPEALS) AND) INTERFERENCES
CAROL A. SPIEGEL Administrative Patent Judge	)

CAS/kis

APPENDIX

1. A test strip, comprising:

a first layer comprising an indicator reagent impregnated into a porous substrate;

a second layer, overlying the first layer, comprising a reactive reagent, the indicator reagent and the reactive reagent being jointly reactive with glucose to produce a measurable output in the event that glucose is present in the liquid sample;

a third layer, overlying the second layer on a side opposite the first layer, comprising a spreading agent that promotes the spreading of a liquid upon the third layer; and

an inert backing overlying the third layer, the backing having an aperture therethrough to the third layer, the aperture being in registry with the first layer, the second layer, and the third layer.

2. The test strip of claim 1, wherein the porous substrate is a nylon membrane.

3. The test strip of claim 1, wherein the indicator is DMAB (3-dimethylaminobenzoic acid).

4. The test strip of claim 1, wherein the reactive reagent is selected from the group consisting of glucose oxidase and peroxidase.

5. The test strip of claim 1, wherein the spreading agent is selected from the group consisting of cellulose acetate and diatomaceous earth.

6. A test strip, comprising:

a first layer comprising an indicator reagent impregnated into a porous substrate;

a second layer, overlying the first layer, comprising a reactive reagent and a substance promoting the spreading of a liquid upon the second layer, the indicator reagent and the reactive reagent being jointly reactive with glucose to produce a measurable output in the event that glucose is present in the liquid sample; and

an inert backing overlying the second layer, the backing having an aperture therethrough to the second layer, the aperture being in registry with the first layer and the second layer.

7. The test strip of claim 6, wherein the porous substrate is a nylon membrane.

8. The test strip of claim 6, wherein the indicator reagent is DMAB.

9. The test strip of claim 6, wherein the reactive reagent is selected from the group consisting of glucose oxidase and peroxidase.

10. The test strip of claim 6, wherein the spreading agent is selected from the group consisting of cellulose acetate and diatomaceous earth.

11. A multilayer test strip, comprising:

a first layer comprising an indicator reagent impregnated into a porous substrate, wherein the indicator reagent is DMAB;

a second layer, overlying the first layer, comprising a reactive reagent that reacts with glucose in human blood, the reactive reagent being selected from the group consisting of glucose oxidase and peroxidase, and

a third layer, overlying the second layer, comprising a spreading agent that promotes the spreading of a droplet of blood upon the third layer; and

an inert backing overlying the third layer, the backing layer having an aperture therethrough to the third layer, the aperture being in registry with the first layer, the second layer, and the third layer.

12. A multilayer test strip, comprising:

a first layer comprising an indicator reagent impregnated into a porous substrate, wherein the indicator regent is DMAB;

a second layer, overlying the first layer, comprising

a reactive reagent that reacts with glucose in human blood, the reactive reagent being selected from the group consisting of glucose oxidase and peroxidase, and

a spreading agent that promotes the spreading of a droplet of blood upon the second layer; and

an inert backing overlying the second layer, the backing having an aperture therethrough to the second layer, the aperture being in registry with the first layer and the second layer.

13. A test strip, comprising:

a reaction unit layer structure, comprising

means for determining the presence of an active species in a liquid sample, and

spreadability enhancing material means for causing a droplet of liquid to spread across a top surface of the reaction unit layer structure; and

a backing having an aperture therein, to which the reaction unit is affixed with the top surface contacting the backing, the spreadability enhancing material means serving to cause a droplet of liquid placed into the aperture to spread across the full extent of the aperture.

14. A method for preparing a test strip, comprising the steps of:

providing a porous substrate;

providing an indicator solution containing the indicator DMAB [3-dimethylaminobenzoic acid], the indicator solution having a sufficiently low viscosity that it is penetrable into the porous substrate;

introducing the indicator solution into the porous substrate;

drying the indicator solution within the porous substrate;

providing a reactive reagent solution containing a reagent selected from the group consisting of glucose oxidase and peroxidase, the solution having a sufficiently high viscosity that it is not penetrable into the porous substrate;

applying the reactive reagent solution as a reactive reagent layer to a surface of the porous substrate;

drying the reactive reagent within the reactive reagent layer; and

attaching the porous substrate to a backing having an aperture therethrough, with the applied layer adjacent to the backing and the porous substrate remote from the backing.

15. The method of claim 14, wherein the step of providing a reactive reagent solution includes the step of

mixing a spreading solution into the reagent solution.

16. The method of claim 14, including the additional steps, after the step of drying the reactive reagent and before the step of attaching the porous substrate, of

providing a spreading solution containing a spreading agents; and

applying the spreading solution as a spreading layer to the reactive reagent layer.

17. A test strip prepared by the method of claim 14.

18. A test strip prepared by the method of claim 15.

19. A test strip prepared by the method of claim 16.

GREGORY O. GARMONG
P.O. BOX 12460
ZEPHYR COVE, NEVADA 89448